

**NOT FOR CITATION**

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

EDWARDS LIFESCIENCES LLC, et al.,

Plaintiffs,

No. C 03-03817 JSW

v.

COOK INCORPORATED, et al.,

Defendants.

**ORDER GRANTING W.L. GORE  
& ASSOCIATES, INC.'S MOTION  
FOR SUMMARY JUDGMENT OF  
NON-INFRINGEMENT**

**INTRODUCTION**

Now before the Court for consideration is the Motion for Summary Judgment of Non-Infringement filed by Defendant W.L. Gore & Associates, Inc. ("Gore"). Having considered the parties' papers, relevant legal authority, and the record in this case, the Court finds the matter suitable for disposition without oral argument. *See* N.D. Civ. L.R. 7-1(b). The Court GRANTS Gore's motion.

**BACKGROUND**

Plaintiffs, Edwards Lifesciences LLC ("Edwards") and Endogad Research PTY Limited ("Endogad") (collectively "Edwards"), filed this suit alleging that Defendants, Cook Incorporated and Gore, infringe U.S. Patent Nos. 6,582,458 ("the '458 Patent"), 6,613,073 ("the '073 Patent"), 6,685,736 ("the '736 Patent"), and 6,689,158 ("the '158 Patent") (collectively the "patents-in-suit"). The patents-in-suit relate to devices for treating aneurysms, and in particular abdominal aortic aneurysms, and occlusive disease without resort to "open" surgery.

On March 14, 2007, the Court held a claim construction hearing, pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). On July 23, 2007, the Court issued its Claim Construction Order, in which it construed several of the disputed claim terms to require “malleable” wires. (*See* Claim Construction Order at 13:1-16:8, 17:17-22:11, 24:5-26:11.) In that Order, the Court stated:

[T]he Court concludes that the inventors disclaimed self-expanding wires in the specification. The inventors describe prior art intraluminal grafts as being comprised of “a sleeve in which is disposed a plurality of self expanding wire stents.” (‘458 Patent, col. 1, ll. 20-22.) They then state that “[t]here are a number of problems associated with such known grafts,” including the “lack of precise control of the expansion of the graft in the lumen.” The inventors then state that their invention is “directed to an alternative form of intraluminal grafts which provides an alternative to the known grafts.” (*Id.*, col. 1, ll. 32-42.) Thereafter, the inventors describe the wires that form part of the invention as malleable or state that the device is expanded by use of balloons. (*See, e.g., id.*, col. 1, ll. 49, 60-63, col. 2, ll. 8-15, col. 3, ll. 8-10, col. 5, ll. 32-36, 58-60, 66-67, col. 6, ll. 5-7.) Thus, when the Court reads the claims in light of the specification, it concludes that a person of ordinary skill in the art would clearly understand that this invention requires malleable, rather than resilient, wires.

(Claim Construction Order at 15:21-16:4.)

Edwards accuses two of Gore’s products of infringing the patents-in-suit: (1) the Gore Excluder Bifurcated Endoprosthesis (“Excluder”); and (2) the Gore TAG Thoracic Endoprosthesis (“TAG”). The focus of Gore’s motion is on the nature of the wires and whether they are “malleable” under the Court’s Claim Construction. Gore asserts they are not. Edwards asserts that they are.

It is undisputed that, in order to deploy and implant the accused devices, they are compressed and constrained within a sheath, which is part of a delivery catheter. This delivery catheter is inserted into a patient’s vessel, pushed to a diseased portion of the vessel, and, after the accused device is positioned satisfactorily, the sheath is withdrawn. As the pressure of the sheath is removed from the accused device, the wires regain their original shape and expand to fit within the vessel. (*See, e.g.,* Declaration of Harry C. Marcus in Support of Gore’s Motion for Summary Judgment, Ex. B (Excerpts of Excluder Clinical Training and Qualification Program Materials including Instructions for Use (“IFUs”) at G 82904, G 82916-17, G 82948-49, G 82992-94, G 83004-06), Ex. C (Excerpts of TAG Clinical Training Program Materials

including IFUs at G 82691; Ex. D (Deposition of Michael J. Vonesh, P.E., Ph.D. (“Vonesh Depo.”) at 41:17-43:14, 49:2-20; *see also* Docket No. 711 (Declaration of Thomas Hankinson in Support of Plaintiffs’ Statement of Facts Regarding Accused Gore Products (“Hankinson Decl.”), Ex A (Excluder Clinical Training Program Materials and IFUS); Ex. B (TAG Clinical Training Materials and IFUs).)

In sum, the wires in Gore’s accused devices initially expand within a vessel because of a release of pressure upon them, rather than by an exertion of pressure upon them. (*See* Docket No. 712 (Declaration of Kim Hodgson (“Hodgson Decl.”), ¶ 4 (“[e]ach of the accused products has wires that initially cause the graft material to self-expand after release of a constraining PTFE panel”).)

It also is undisputed that a balloon can be used during deployment and implantation of the accused devices. The record further supports a conclusion that Gore recommends that the balloon be used. (*See, e.g.*, Marcus Decl., Ex. D (Vonesh Depo. at 49:2-20, 67:2-23); Hodgson Decl., ¶¶ 4-5.) However, the parties dispute whether this fact creates a genuine issue of fact as to whether the wires in Gore’s accused devices are “malleable.”

The Court shall discuss additional facts as necessary in the analysis.

### ANALYSIS

On March 18, 2008, the Court granted Cook’s motion for summary judgment. Edwards concedes that, under the Court’s reasoning in that Order, Gore’s products do not infringe the patents-in-suit. (*See, e.g.*, Opp. Br. at 1:2-10.) To provide a complete record, the Court shall articulate in full its reasons for granting Gore’s motion.

#### **A. Legal Standards Applicable to Motions for Summary Judgment.**

Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Union States Gypsum Co. v. Nat’l Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996). The burden of demonstrating the absence of any genuine issue of material fact rests with the moving party. *SRI Int’l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1116 (Fed. Cir. 1985). In order to defeat summary judgment, the non-moving party must do “more than simply show that there is some

metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rather, the non-moving party must set forth “specific facts showing that there is a genuine issue for trial.” Fed. R. Civ. P. 56(c); *Matsushita Elec.*, 475 U.S. at 587.

**B. Gore’s Motion for Summary Judgment is Granted.**

There are two steps in an infringement analysis: (1) construing the claims of the patent in suit; and (2) comparing the properly construed claims to the accused products. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (*en banc*); *see also SafeTCare Mfg., Inc. v. Tele-Made, Inc.*, 497 F.3d 1262, 1268 (Fed. Cir. 2007). The Court has construed the claims. Thus, the Court now must determine whether, under its construction, Gore’s accused devices fall within the scope of those claims.

To meet its burden on the second prong of the infringement analysis, Edwards “‘must show the presence of every element or its substantial equivalent in the accused device.’” *Terlep v. Brinkman Corp.*, 418 F.3d 1379, 1384 (Fed. Cir. 2005) (quoting *Wolverine World Wide, Inc. v. Nike, Inc.*, 38 F.3d 1192, 1199 (Fed. Cir. 1994)). Edwards bears the burden of proving infringement, either literally or under the doctrine of equivalents, by a preponderance of the evidence. *See, e.g., Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

**1. Edwards Cannot Show that Gore’s Accused Devices Literally Infringe the Patents-in-Suit.**

Gore argues that Edwards cannot show that Gore’s accused devices contain malleable wires. “Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). ... If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law.” *Bayer AG*, 212 F.3d at 1247 (citation omitted). Although Edwards concedes that, based on the Court’s Order granting Cook’s motion for summary judgment, Gore’s devices infringe, it once again argues that the plain meaning of the word “malleable” means deformable. (*See Opp. Br.* at 2:17-21; Docket 713 (Declaration of Charles A. Taylor in Support of Plaintiffs’ Statement of Facts re Accused Gore Devices (“Taylor Decl.”), ¶ 2).) Using that definition, Edwards contends that the wires in

the accused devices are malleable, because the wires can be shaped before they are attached to graft material. Edwards also argues that the wires may become deformed when the accused devices are inserted into a vessel. (*See, e.g.*, Hodgson Decl., ¶ 8; Taylor Decl., ¶¶ 2, 4-5.)

As the Court concluded in its Order granting Cook's motion, under a plain meaning of the term "malleable," Edwards' argument might be well taken. In the specification, however, the inventors state that "[t]he wires are maleable [*sic*] and may be bent into any desired shape, *ie they are not resilient to any substantial extent so that they have to be physically expanded into contact with the aorta rather than expanding by virtue of their own resilience.*" (Marcus Decl., Ex. A ('458 Patent, col. 5, ll. 32-35 (emphasis added)).) This phrase uses the term "*i.e.*," not "and." The term "*i.e.*" is "[a]n abbreviation for '*id. est.*,' that is; that is to say." *See* Blacks Law Dictionary at 746 (6<sup>th</sup> ed. 1990). Thus, by using the signal "*i.e.*" the inventors explained that "malleable" meant "not resilient to any substantial extent so that [the wires] have to be physically expanded into contact with the aorta rather than expanding by virtue of their own resilience." ('458 Patent, col. 5, ll. 32-35.) *See, e.g., Abbott Labs v. Novopharm Ltd.*, 323 F.3d 1324, 1327, 1330 (Fed. Cir. 2003). The Court relied on the inventors' definition of malleable when it construed the claims.

Edwards also repeats its argument that, even if one does not use the plain meaning of the term malleable, Gore's accused devices nonetheless infringe the patents-in-suit because Gore recommends using a balloon once a device is situated within a vessel. Edwards again argues that this demonstrates that the wires are malleable because they are capable of being deformed by pressure. (*See, e.g.*, Hodgson Decl., ¶ 8; Taylor Decl., ¶ 5 ("In my opinion, the expansion of the graft material in both the Excluder and TAG devices likely causes expansion of the wires because the wires are tightly bonded to the graft. This is especially true in the overlap region of the two graft portions, which are not typically placed against the vessel wall, or in the case where the balloon is used to fix a leak. Thus, expansion of the balloon would be a meaningless step if the graft and wires were not caused to expand.").)

Gore contends that the balloon does not cause the wires to expand, but rather is used to smooth out the graft material. (*See, e.g.*, Marcus Decl., Ex. D (Vonesh Depo. at 44:13-20,

67:11-20, 102:21-103:15).) Gore also notes that the diameter of the accused devices is designed to be larger than the vessels into which they are inserted. According to Gore, for this reason, the wires would continue to self expand if they had room and thus, the use of the balloon does not render them “malleable.” (*See, e.g., id.* (Vonesh Depo. at 103:22-105:10).)

Once again, even when the Court considers the evidence regarding the use of the balloon in the light most favorable to Edwards, the Court concludes that it demonstrates only that once the accused devices have been placed within a vessel and the wires have expanded *on their own*, the balloon may be used to finish a seal or straighten out the fabric body of a graft. However, the definition of malleable in the patents-in-suit focuses on the manner in which the wires expand and whether they are capable of expanding without the exertion of pressure upon them. Under the Court’s construction of the claims, the Court concludes that no reasonable jury could conclude that Gore’s accused devices contain “malleable” wires. Gore, therefore, is entitled to judgment in its favor on this basis.

**2. Edwards Cannot Show the Accused Devices Infringe the Patents-in-Suit Under the Doctrine of Equivalents.**

“Under the doctrine of equivalents, ‘a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is equivalence between the elements of the accused product or process and the claimed elements of the patented invention.’” *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1357 (Fed. Cir. 2005) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997)).

The doctrine of equivalents thereby recognizes that:

[t]he language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty. If patents were always interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying. For this reason, the clearest rule of patent interpretation, literalism, may conserve judicial resources but is not necessarily the most efficient rule. The scope of a patent is not limited to its literal terms but instead embraces all equivalents described.

1 *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). Although a  
2 patentee is entitled to argue that an accused device is equivalent to his or her claimed invention,  
3 the ability to argue infringement by equivalence is not without limitations.

4 One limit on the doctrine of equivalents is the “all elements” rule. The “all  
5 elements” rule attempts to balance the doctrine of equivalents with the basic  
6 patent law principle that claim language defines the scope of an invention  
7 and every limitation is material.

8 Each element contained in a patent claim is deemed material to  
9 defining the scope of the patented invention, and thus the doctrine of  
10 equivalents must be applied to individual elements of the claim, not  
11 to the invention as a whole. It is important to ensure that the  
12 application of the doctrine, even as to an individual element, is not  
13 allowed such broad play as to effectively eliminate that element in its  
14 entirety.

15 *Warner-Jenkinson*, 520 U.S. at 29. Thus, as a practical matter, the “all  
16 elements” rule informs a doctrine of equivalents analysis by requiring that  
17 equivalence be assessed on a limitation-by-limitation basis, rather than from  
18 the perspective of the invention as a whole, and that no limitation be read  
19 completely out of the claim. [*Freedman Seating Co.*, 420 F.3d at 1358.]

20 In *Warner-Jenkinson*, the Supreme Court provided guidance for determining  
21 when resort to the doctrine of equivalents is precluded as a matter of law.  
22 First, the Court noted that “[w]here the evidence is such that no reasonable  
23 jury could determine two elements to be equivalent, district courts are  
24 obliged to grant partial or complete summary judgment.” *Warner-Jenkinson*,  
25 520 U.S. at 39 (citing Fed. R. Civ. P. 56; *Celotex*, 477 U.S. at 322-23)).  
26 Second, the Court noted that “under the particular facts of a case, ... if a  
27 theory of equivalence would entirely vitiate a particular claim element,  
28 partial or complete judgment should be rendered by the court.” *Id.* at 39 n.8.

19 *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1016 (Fed. Cir. 2006).

20 The Federal Circuit has noted that “[t]here is no set formula for determining whether a  
21 finding of equivalence would vitiate a claim limitation, and thereby violate the all limitations  
22 rule. Rather, courts must consider the totality of the circumstances in each case and determine  
23 whether the alleged equivalent can be fairly characterized as an insubstantial change from the  
24 claimed subject matter without rendering the pertinent limitation meaningless.” *Freedman*  
25 *Seating*, 420 F.3d at 1359.

26 Edwards argues that “resilient” wires can perform the same function as “malleable”  
27 wires with the same result. See *Warner-Jenkinson*, 520 U.S. at 39-40. Edwards again offers the  
28 opinion of Dr. Taylor, who contends that the wires in Gore’s accused devices are equivalent to



1 the wires in the patents-in-suit and avers that the resilient wires in Gore's products "provide a  
2 flexible structure that permits one individual part of the graft to be overlapped and anchored  
3 within the other individual part of the graft, and provide a seal between the two portions."  
4 (Taylor Decl., ¶ 6.) Dr. Taylor also opines that "the other function of the wire is to provide  
5 support along the length of the graft material." (*Id.*) He further avers that Gore's resilient wires  
6 perform these each of these functions in the same manner as the patents-in-suit, namely by  
7 expansion. (*Id.*, ¶¶ 6-7.)

8         Once again, the Court finds Edwards' argument on the doctrine of equivalents to be  
9 analogous to the argument presented to, and rejected by, the Federal Circuit in *Tronzo v.*  
10 *Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998). In that case, the claims of the patent-in-suit were  
11 directed to "artificial hip sockets that include cup implants adapted for insertion into an  
12 acetabular, or hip, bone." *Id.* at 1156. Two of the asserted claims required a conical shaped  
13 cup, but the plaintiff argued at trial that the defendant's hemispherical shaped cup functioned in  
14 the same way as a conically shaped cup, and the jury agreed. *Id.* at 1160. On appeal, the  
15 Federal Circuit concluded that to find that "any shape would be equivalent to the conical  
16 limitation," would vitiate that claim limitation and would violate the all-elements rule. *Id.* Here  
17 too, Edwards' argument is premised upon a finding that any wire would be the equivalent of a  
18 "malleable" wire. If, however, the Court were to adopt that argument and conclude that  
19 "resilient" wires would be equivalent to "malleable" wires, it would vitiate the malleable  
20 limitation the Court concluded is required by the claims. Furthermore, the Court also concluded  
21 that Edwards disclaimed the use of resilient wires. When a patentee has disavowed or  
22 disclaimed certain subject matter from the scope of the claims, that subject matter cannot be  
23 considered an equivalent. *See J&M Corp. v. Harley Davidson, Inc.*, 269 F.3d 1360, 1366 (Fed.  
24 Cir. 2001) ("The scope of equivalents may [] be limited by statements in the specification that  
25 disclaim coverage of certain subject matter.")

26         Accordingly, the Court concludes that Edwards cannot, as matter of law, show that  
27 Gore's accused devices infringe the patents-in-suit under the doctrine of equivalents. Gore,  
28 therefore, is entitled to judgment in its favor on this basis as well.

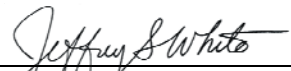


**CONCLUSION**

For the foregoing reasons, Gore's motion for summary judgment of non-infringement is GRANTED.

**IT IS SO ORDERED.**

Dated: September 15, 2008

  
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JEFFREY S. WHITE  
UNITED STATES DISTRICT JUDGE